UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

A10CA883 SS

UNITED STATES OF AMERICA,
STATE OF CALIFORNIA,
STATE OF DELAWARE,
STATE OF FLORIDA,
STATE OF GEORGIA,
STATE OF HAWAII,
STATE OF ILLINOIS,
STATE OF INDIANA,
STATE OF LOUISIANA,
COMMONWEALTH OF MASSACHUSETTS,
STATE OF MICHIGAN,
STATE OF NEVADA,
STATE OF NEW HAMPSHIRE,
STATE OF NEW JERSEY,
STATE OF NEW MEXICO,
STATE OF NEW YORK,
STATE OF OKLAHOMA,
STATE OF RHODE ISLAND,
STATE OF TENNESSEE,
STATE OF TEXAS,
COMMONWEALTH OF VIRGINIA,
STATE OF WISCONSIN,
and DISTRICT OF COLUMBIA,

ex rel. DESALLE BUI,

Plaintiffs,

v.

VASCULAR SOLUTIONS, INC.

Defendant.

COMPLAINT
FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

On behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of

Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Rhode Island, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, and the District of Columbia (collectively the "States"), Plaintiff and Relator Desalle Bui ("Mr. Bui" or "Relator") files this *qui tam* complaint against Defendant Vascular Solutions, Inc. ("Vascular" or "Defendant") and alleges as follows:

I. INTRODUCTION

A. Federal Law Claims.

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America in connection with Vascular Solutions' marketing of certain medical devices, including "off-label" marketing, in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA").

2. Pursuant to the FCA, Relator seeks to recover, on behalf of the United States of America, damages and civil penalties arising from false or fraudulent claims that Defendant submitted or caused to be submitted to Federal Government funded health insurance programs for Defendant's medical device procedures, including payments made by Medicare, Medicaid, the Federal Employees Health Benefits Program ("FEHBP"), the managed care component of the United States Department of Defense Military Health System (TRICARE), and the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA).

B. State Law Claims.

3. This is also an action to recover double and treble damages and civil penalties on behalf of the named States arising from the conduct of Defendant who: (a) made, used or

presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the States; and/or (b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the States, all in violation of each State's respective false claims act or similar statute. The false or fraudulent claims, statements and records at issue involve payments made by health insurance programs funded by these State governments, including Medicaid.

4. The statutes of the States under which Relator brings these related actions are the:

a. California False Claims Act, Cal. Govt. Code § 12651 *et seq.*;

b. Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.*;

c. Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*;

d. Georgia False Medicaid Claims Act, Ga. Code. Ann. § 49-4-168.1 *et seq.*;

e. Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*;

f. Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*;

g. Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*;

h. Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*;

i. Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, § 5A *et seq.*;

j. Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*;

k. Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*;

l. New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b;

m. New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*;

n. New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*, and New Mexico Fraud Against Tax Payers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*;

o. New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*;

p. Oklahoma Medicaid False Claims Act, 63 Okla. St. Ann. § 5053 *et seq.*;

q. The State False Claims Act (Rhode Island), R.I. Gen. Laws § 9-1.1-1 *et seq.*;

r. Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*;

s. Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.002;

t. Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*;

u. Wisconsin False Claims for Medical Assistance Law, Wisc. Stat. § 20.931; and the

v. District of Columbia False Claims Act, D.C. Code Ann. § 2-308.03 *et seq.*

II. SUMMARY OF THE ALLEGATIONS

5. Vascular Solutions has defrauded the Government by marketing its endovenous laser therapy products for uses outside of those which have been cleared by the U.S. Food and Drug Administration ("FDA"), by providing kickbacks to physicians to promote such uses, and by instructing physicians as to how to bill Government health care programs, such as Medicare and Medicaid, for these "off-label" uses.

6. Vascular Solutions is a publicly traded medical device company focused on coronary and peripheral vascular procedure products, with 2009 net sales exceeding $66 million and a distribution network covering over 35 countries.

7. Vascular Solutions has five major product categories -- hemostat products, extraction catheters, vein products, specialty catheters and access products. Vascular has developed over 40 products for commercialization.

8. Vascular's vein products include the Vari-Lase Endovenous Laser Console ("laser console"), the Vari-Lase Procedure Kits ("procedure kits") and accessories (collectively the "Vari-Lase products").

9. Vascular launched its first endovenous laser product, the Vari-Lase procedure kit, in July of 2003. In December 2003, Vascular received FDA clearance for the Vari-Lase laser console. Since 2004, Vascular has expanded its vein product line with various items, including its Vari-Lase Bright Tip laser fiber, launched in April of 2007, and its Vari-Lase Short Procedure Kit, launched in the first quarter of 2008.

10. Vascular's market share is approximately 35% of the endovenous laser therapy market.

11. In 2009, revenue from sales of Defendant's endovenous laser therapy products was approximately $11 million.

12. The Vari-Lase products are designed for the treatment of venous reflux disease, which occurs when the valves that normally force blood flow back up towards the heart no longer function, causing blood to pool up in the legs and the veins of the legs to become distended. Symptoms of venous reflux disease include the swelling and distortion of the legs' main superficial trunk veins, the greater and lesser saphenous veins, a condition commonly known as varicose veins. The superficial veins lie close to the surface of the skin and are connected to the veins which lie deep in the body by horizontal veins called perforator veins.

13. Endovenous laser ablation involves the placement of a needle in the diseased vein through which a guide-wire and sheath are introduced into the vein. A laser fiber is placed through the sheath and into the vein, cauterizing the vein in order to seal it.

14. In 2004, the Centers for Medicare and Medicaid Services ("CMS") established payment rates for endovenous laser procedures under two dedicated reimbursement codes, which would become effective on January 1, 2005.

15. Upon information and belief, approximately 60 percent of patients undergoing endovenous vein procedures using Vascular's laser products are Medicare beneficiaries and approximately 20 percent are Medicaid beneficiaries.

16. Medicare non-facility reimbursement rates for an endovenous laser therapy first vein treatment, (Health Common Procedure Coding System ("HCPCS") number 36478), averaged $1,700 in 2008 and $1,400 in 2009.

17. Upon information and belief, Vari-Lase laser therapy patients undergo an average of four to six laser ablation procedures.

18. Under the Food, Drug, and Cosmetic Act (the "FDCA"), a manufacturer of medical devices classified in Class II or III of its three-tiered risk classification system must generally obtain FDA marketing clearance or approval before introducing a new medical device into the market. Any modification to a device that could significantly affect a device's safety or effectiveness, including a significant change in its intended use, requires that the manufacturer obtain a new or expanded clearance or approval.

19. The Vari-Lase procedure kits and accessories, which have been categorized as Class II devices, are cleared by the FDA for the treatment of varicose veins and varicosities

associated with reflux of the great saphenous vein and for the treatment of incompetence and reflux of the superficial veins in the lower extremity.

20. Vascular, however, is marketing and otherwise promoting the use of Vari-Lase products, including the Vari-Lase laser console, procedure kits and accessories, for the treatment of reflux symptoms in perforator veins, the horizontal veins which connect the surface veins with those of the deep venous system, without FDA clearance to do so.

21. Upon information and belief, Vascular does not have, nor has it sought, FDA clearance for the treatment of refluxing perforator veins for its Vari-Lase products. In fact, no laser therapy has been approved by the FDA for the treatment of perforator veins. Only radiofrequency treatment has been cleared for the treatment of perforator veins, because it does not pose the same potential risk of harm to the deep venous system that the direct delivery of the laser treatment poses, due to its dispersed method of energy delivery. Vascular Solutions competitor VNUS, whose procedure involves radiofrequency energy rather than that generated by a laser, is the only company to have received marketing clearance for the use of an endovenous medical device for the treatment of perforator veins.

22. Upon information and belief, at least 25% of Vari-Lase laser ablation procedures involve off-label use for the treatment of perforator veins.

23. Additionally, in an effort to increase physicians' commitment to Vascular's products over those of its competitors (*e.g.*, Diomed Inc. and Angiodynamics Inc., which merged in 2008), Vascular has tacitly encouraged the re-use of its single-use Vari-Lase fibers, cleared by the FDA for one-time use only, by making the less expensive sheaths through which the fibers must be passed as part of the laser procedure available for purchase separately from the single-use fibers.

24. Whereas physicians can only buy sheaths and fibers together as part of complete procedure kits from Vascular's competitors in the endovenous laser therapy field, physicians are able to buy additional Vari-Lase sheaths without purchasing new fibers from Vascular, and thus are able to re-use, and do re-use, the expensive Vari-Lase single-use fibers for multiple procedures, contrary to FDA approval.

25. In addition to engaging in activities aimed at promoting its Vari-Lase products for uses outside of those which have been cleared by the FDA, Vascular has provided kickbacks to physicians in the form of free procedure kits with the purchase of Vari-Lase laser consoles.

26. In sum, and as described more fully herein, Vascular violated the federal and state False Claims Acts by engaging in fraudulent, deceptive, and illegal marketing, sales and business practices which resulted in the federal and state governments paying for medical procedures they should not have paid for, or overpaying for procedures they paid for or reimbursed. The resulting damages to the federal and state governments – and the taxpayers – are potentially in the millions of dollars.

II. JURISDICTION AND VENUE

27. Pursuant to 28 U.S.C. § 1331, this Court has jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particularly the False Claims Act, 31 U.S.C. § 3729 *et seq*.

28. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the States on the ground that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

29. In addition, the FCA specifically confers jurisdiction upon United States District Courts under 31 U.S.C. § 3732. This court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in the Western District of Texas.

30. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because certain of the acts complained of herein occurred in the Western District of Texas.

31. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and Defendant has sufficient minimum contacts with the United States of America.

32. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint has been filed *in camera* and will remain under seal for a period of at least 60 days and shall not be served on the Defendant until the Court so orders.

33. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator must provide the Government with a copy of the Complaint and/or a written disclosure of substantially all material evidence and material information in his possession contemporaneous with the filing of the Complaint. Relator has complied with this provision by serving copies of this Complaint upon the Honorable John E. Murphy, United States Attorney for the Western District of Texas, and upon the Honorable Eric H. Holder, Attorney General of the United States.

34. Relator is not aware that the allegations in this Complaint have been publicly disclosed. Further, to the extent Relator is aware of any public disclosures, this Complaint is not based on such public disclosures. In any event, this Court has jurisdiction under 31 U.S.C. § 3730(e)(4) because the Relator is an "original source" because he has provided his information voluntarily to the Government before filing this Complaint, and has knowledge which is both direct and independent of any public disclosures to the extent they may exist.

IV. THE PARTIES

35. Relator Desalle Bui is a resident of Gilbert, Arizona. He has a B.A. in Business Administration and Accounting from the University of Washington.

36. Mr. Bui was employed by Vascular Solutions as an Account Manager in Phoenix, Las Vegas and Albuquerque from February 2008 through May 2009, when he left the company on his own accord. The Regional Manager overseeing Mr. Bui's territory was based in Austin, Texas.

37. Mr. Bui was a top ranking sales representatives for Vascular, tripling sales in his territory in 2008. He was responsible for selling medical devices, capital equipment and disposables to hospitals and vein centers, and for assisting and training surgeons and staff on proper surgical techniques using the Vari-Lase endovenous laser therapy products. Mr. Bui has worked in pharmaceutical and medical sales and sales management since March of 2001.

38. From his employment at Vascular, Mr. Bui gained direct and personal knowledge of the facts alleged herein.

39. Defendant Vascular Solutions, Inc. was incorporated in the state of Minnesota in December 1996, and began operations in February 1997. It is headquartered in Minneapolis, Minnesota, and is publicly traded on the NASDAQ Global Market.

40. Vascular Solutions is an interventional medical device company focused on coronary and peripheral vascular procedure products and sealing technologies, with 2009 net sales exceeding $66 million and a distribution network covering over 35 countries. As of December 31, 2009, Vascular reported cash and cash equivalents valued at approximately $17.8 million.

V. GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT

A. The False Claims Act.

41. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. Further clarifying amendments were adopted in May 2009.

42. The FCA imposes liability upon any person who "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval"; or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim"; or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(A), (B), (G). Any person found to have violated these provisions is liable for a civil penalty of up to $10,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

43. Significantly, the FCA imposes liability where the conduct is merely "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b)(1).

44. The FCA also broadly defines a "claim" as one that "includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse

such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2)(A).

45. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene in the action. 31 U.S.C. § 3730(b).

46. The marketing of medical devices for off-label use and the payment of kickbacks to physicians by a party which seeks reimbursement from a federal government health program, or causes another party to seek such reimbursement, while certifying or impliedly certifying compliance with the Food, Drug and Cosmetics Act and the Anti-Kickback Statute, or causing another party to do so, constitutes a violation of the FCA.

B. FDA Regulation of Medical Devices.

47. The United States Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, passed by Congress in 1938, and amended several times since then, gives the FDA the authority to oversee the safety and effectiveness of food, drugs, and cosmetics.

48. Pursuant to the FDCA, the FDA regulates the marketing of medical devices. The FDA classifies medical devices according to their perceived risk using a three-tiered system (class I, II, or III). 21 U.S.C. § 360c.

49. Before a medical device manufacturer introduces a class II or III device into commercial distribution, the manufacturer must generally obtain marketing clearance or approval from the FDA. 21 U.S.C. § 360c.

50. Section 510(k) of the FDCA establishes premarket notification requirements ("PMN" or "510(k)" requirements) for the clearance of medical devices. 21 U.S.C. § 360(k); 21 C.F.R. 807.87. In the 510(k) application, the manufacturer of the new device must demonstrate that it is at least as safe and effective, or "substantially equivalent" for the stated indications for use, to a legally marketed "predicate" device. Most class II devices require PMA clearance before they may be marketed.

51. If the device is determined to meet the "substantial equivalence" requirement, then it may be marketed, subject to the general controls provisions of the Act. These controls include requirements for registration and labeling, and prohibitions against misbranding and adulteration.

52. If the device does not meet the "substantial equivalence" requirement, then approval of the device by the FDA pursuant to a premarket approval application ("PMA"), involving the more complex review applied to Class III devices, may be required.

53. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance, or might even require premarket approval. 21 U.S.C. § 360; 21 C.F.R. 807.81(a)(3)(ii).

54. The FDCA prohibits the failure to submit a required 510(k), and devices lacking 510(k) approval are considered misbranded under the FDCA, and its manufacturer in violation of the law. 31 U.S.C. §§ 331(p), 352(o). Additionally, every new device that lacks a necessary 510(k) is considered by operation of law to be a Class III device needing premarket approval, and since devises lacking a necessary PMA are considered to be adulterated under the FDCA, devices lacking a required 510(k) are also considered to be adulterated under the FDCA. 21

U.S.C. §§ 360c(f)(1), 351(f)(1)(B)(i).

55. The FDCA provides for a civil penalty of up to $15,000 for each violation of the Act related to a medical device, not to exceed $1,000,000 adjudicated in a single proceeding. 21 U.S.C. §333(f).

C. Federal Government-Funded Health Assistance Programs.

1. Medicare.

a. Generally.

56. Medicare is a federal government-funded medical assistance program, primarily benefiting the elderly, that was created in 1965 when Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* Medicare is administered by the federal Centers for Medicare and Medicaid Services ("CMS"), known prior to 2001 as the Health Care Financing Administration, which is a division of the U.S. Department of Health and Human Services ("HHS").

2. Medicaid.

a. Generally.

57. The Medicaid program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the medically needy aged, the blind, the disabled and needy families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both federal and state monies, (collectively referred to as "Medicaid Funds"), with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). At the federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a state Medicaid agency to administer the program. Each state is permitted, within certain parameters, to design its own medical assistance

plan, subject to approval by the HHS.

3. General Provisions Applicable to Both Medicare and Medicaid.

a. Prohibitions Against Claims for Services that are Not Medically Necessary or are Otherwise False or Fraudulent.

58. Federal law prohibits a person from knowingly presenting or causing to be presented to Medicare or Medicaid a claim for a medical or other item or service that the person knows or should know was "not provided as claimed," a claim for such items or services that is "false or fraudulent," or a claim that is "for a pattern of medical or other items or services that [the] person knows or should know are not medically necessary." 42 U.S.C. §§ 1320a-7a(a)(1)(A), (B) & (E). Violation of this section is subject to a civil monetary penalty of $10,000 for each item or service, plus damages measured as three times the amount of each claim submitted, and exclusion from further participation in the programs.

b. The Anti-Kickback Statute.

59. Parties who contract or subcontract with the federal government are subject to the provisions of the Anti-Kickback Act. That law renders it impermissible for any person "to provide, attempt to provide, or offer to provide any kickback," and defines 'kickback' to mean "any money, fee, commission, credit, gift, gratuity, *thing of value*, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor, or subcontractor employee *for the purpose of improperly obtaining or rewarding favorable treatment* in connection with a prime contract or in connection with a subcontract relating to a prime contract." 41 U.S.C. §§ 52-53 (emphasis added). This broad language reflects Congress's intent to prohibit even *attempts* to offer or provide a kickback, and to include a wide array of benefits and activities within its scope.

60. The Anti-Kickback Statute prohibits kickbacks by providing a civil monetary

penalty of $50,000 for each act by an individual or entity that violates 42 U.S.C. § 1320a-7a(a)(7), which defines "[i]mproperly filed claims" as "[a]ny person (including an organization, agency, or other entity . . . that commits an act described in paragraph (1) or (2) of section 1320a-7b(b) of this title." The statute defines "illegal remuneration" (*i.e.*, kickbacks) as:

> (1) whoever knowingly and willfully *solicits or receives* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
>
> * * *
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> * * *
>
> (2) whoever knowingly and willfully *offers or pays* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> * * *
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

42 U.S.C. § 1320a-7b(b) (emphasis added). The offense is also a felony punishable by fines of up to $25,000 and imprisonment for up to five years. 42 U.S.C. § 1320a-7b(b).

61. The Anti-Kickback Statute contains statutory exceptions and regulatory "safe harbors" excluding certain types of conduct from liability. *See* 42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952. None of these statutory exceptions or regulatory safe harbors applies to Defendant's conduct in this matter.

62. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In

addition, the Balanced Budget Act of 1997 amended that Act to impose administrative civil monetary penalties for Anti-Kickback Statute violations: $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

63. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware expensive endovenous laser therapy was prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of the Defendant's wrongdoing.

D. Direct Federal Health Insurance Plans.

1. TRICARE/CHAMPVA.

64. TRICARE, administered by the Department of Defense ("DoD"), is the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

65. Similarly, CHAMPVA, administered by the Department of Veterans Affairs (the "VA"), provides healthcare coverage to qualified families of deceased or 100% disabled

veterans.

2. Federal Employees Health Benefits Plan.

66. The FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. The FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management and collectively pay billions annually in medical benefits and reimbursements.

E. American Medical Association and American College of Physicians Ethics Policies.

67. In recent years, responding to health care companies' providing "increasingly lavish" gifts and payments to doctors in connection with seminars, conferences, and sales representative visits, and entering into relationships both formal and informal that created financial incentives for physicians to prescribe or order particular companies' products or services, the American Medical Association ("AMA") adopted several Ethical Opinions. The AMA's purpose was to discourage physicians from accepting payments, gifts and incentives from industry, to avoid creating "relationship[s] that could influence the use of the company's products."

68. In 1998, with the stated purposes of "achiev[ing] the necessary goals of patient care" and "protect[ing] the role of physicians as advocates for individual patients," the AMA adopted an Ethical Opinion regarding "Financial Incentives and the Practice of Medicine." (Opinion 8.054).

69. Among other things, Opinion 8.054 advised:

(1) [Physicians'] first duty must be to the individual patient. This

> obligation must override considerations of the reimbursement mechanism or specific financial incentives applied to a physician's clinical practice.
>
> (2)(a) [Financial] incentives may create conflicts of interest that can in turn compromise clinical objectivity. . . . [I]t is important to recognize that sufficiently large incentives can create an untenable position for physicians.
>
> (2)(b) The proximity of large financial incentives to individual treatment decisions should be limited in order to prevent physicians' personal financial concerns from creating a conflict with their role as individual patient advocates. . . . [P]hysicians must behave in accordance with prior Council recommendations limiting the potential for abuse. This includes the Council's prohibitions on fee-splitting arrangements, the provision of unnecessary services, unreasonable fees, and self-referral.

70. Similarly, the American College of Physicians' Ethics Manual ("Ethics Manual") advises that physicians receiving compensation as "speakers" or "consultants" could have "potential conflicts of interest" and warned that such arrangements "must not in any way compromise their objective clinical judgment or the best interests of patients. . . ." (Ethics Manual, "Financial Conflicts of Interest").

VI. SPECIFIC ALLEGATIONS

A. Vascular's Illegal Practices.

1. Off-Label Promotion.

a. Marketing for Unapproved Use.

71. At the specific direction of management (including upper management) and with their actual knowledge, Vascular Solutions markets its Vari-Lase laser therapy products "off-label," for use other than that cleared by the FDA, in violation of the FDCA, and ultimately in violation of the False Claims Act.

72. Vascular's endovenous laser therapy products include the Vari-Lase Endovenous Laser Console (or "Vari-Lase 810 Laser Console") and various Vari-Lase Endovenous Laser Procedure Kits, including standard procedure kits, custom procedure kits, flex procedure kits and short procedure kits designed for the treatment of short vein segments. These procedure kits

contain various components used in performing the endovenous laser therapy procedure, including laser fibers, sheaths, guidewires, needles and, in some instances, catheters.

73. The Vari-Lase laser procedure, procedure kits and laser fibers are cleared for "the treatment of varicose veins and varicosities associated with superficial reflux of the Greater Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity." The greater saphenous vein, also called the great saphenous vein, and other superficial veins are the veins that course in the tissue immediately underlying the skin.

74. Since at least in or about 2008, Vascular, has marketed its laser console, laser procedure and short procedure kit, including the Vari-Lase Bright Tip laser fiber, short micro guidewire and short sheath, for the treatment of perforator veins, the veins that connect the superficial veins to the large blood vessels found deep inside the muscles, without FDA clearance.

Vascular Management Knowingly Promotes Off-Label Marketing of "Short Kits" to Treat Perforator Veins, Ignoring the Serious Patient Risks

75. Despite knowing full well that the FDA had not approved Vari-Lase to treat perforator veins, and knowing full well the serious risks of deep vein thrombosis that arise with such off-label treatment, Vascular's management elected to market Vari-Lase short procedure kits and accompanying laser fibers to physicians as "perforator kits," (also known as "short kits"). The Vari-Lase Short Procedure Kit was introduced in or about the first quarter of 2008. The company has promoted the benefits of using the Vari-Lase products for the treatment of perforator veins, while ignoring or downplaying the serious risks. Indeed, according to Relator, Vascular representatives routinely describe Vari-Lase (inaccurately) as the *only* available procedure for the effective treatment of perforator veins. This has become a major selling point in Vascular's marketing of the Vari-Lase laser consoles.

76. Vascular Solutions executives (including upper management) know that the Vari-Lase products are not FDA-approved for treatment of perforator veins, but nonetheless specifically instruct sales reps to market them for that purpose. Management also urges the sales force not to discuss the serious risks of deep-vein thrombosis with doctors, and to downplay such risks if doctors raise concerns.

77. Vascular Solutions holds nationwide sales meetings twice a year, usually at the company's headquarters in Minnesota in July and in Las Vegas in January. Top management presides over these meetings, which the entire company sales force attends. Vascular management holds regional meetings of the sales force during the spring and fall quarters. Relator has attended several such sales meetings, both national and regional.

78. At these meetings, top management of Vascular Solutions, as well as regional and other sales managers, routinely instruct sales reps to market the Vari-Lase products, including the "short kits," for non-indicated treatment of perforator veins. At these meetings, managers openly acknowledge that the FDA had not approved the products for treatment of perforator veins; however, sales reps were nonetheless encouraged to market them for that purpose to doctors.

79. At a sales meeting held in May or June of 2008, Vascular provided its sales representatives with written instructions directing them to introduce the "short vein (perforator) kits" to physicians.

80. The material informs the representatives that Vascular is the only laser company selling any type of perforator kits, and lays out the various ways in which the Vari-Lase procedure and products are preferable to those of Vascular's competitor, VNUS, for the treatment of perforator veins.

81. The material also advises Vascular representatives to read recommended articles on the treatment of perforator veins which they might take with them on laboratory visits.

82. A power point presentation entitled "Treating Perforator Veins!!! An Easier Way" about diagnosing and treating incompetent perforator veins and promoting Vari-Lase products for the treatment of perforator veins was also presented by Vascular to its sales representatives at the Spring 2008 sales meeting.

83. Also in the spring of 2008, an e-mail containing "Tips for Treating Perforator Veins" with advice for best procedure practices and a diagram of the perforator vein anatomy was sent to Vascular sales and clinical representatives.

84. According to Relator, in or about July 2008, the sale of "perforator kits" was discussed during a regional sales representative conference call with regional manager, Kip Theno, in which sales representatives were pressured to sell more laser consoles by promoting the use of the Vari-Lase procedure for the treatment of perforator veins.

85. According to Relator, in or about November 2008, Fred Reuning, then vice-president of marketing for Vari-Lase, told Vascular sales representatives that Vascular had not yet applied for clearance of its products for the treatment of perforator veins, due to poor results of its then current clinical trials.

86. According to Mr. Reuning, the clinical trials showed that the use of Vari-Lase products for the treatment of perforator veins resulted in an increased risk of deep vein thrombosis, the potentially harmful, or even deadly, formation of blood clots in the deep venous system.

87. Relator's allegations regarding Fred Reuning and his statements about the perforator vein clinic trials are corroborated by a former Vascular representative for parts of Texas and New Mexico with the initials E.P.

88. E.P. stated that at "break-out" sessions during Vascular's annual sales meetings, Fred Reuning and Tony Jakubowski, a vascular clinical liaison who was also in charge of Vascular's vein business, would make presentations on the use of Vascular's "short kits" to treat perforator veins.

March 2009 Regional Sales Meeting in Austin, Texas

89. Shane Carlson was (and is, at the date of this filing) a Regional Manager for Vascular Solutions, supervising sales reps in Texas, New Mexico, and Arizona. Carlson is based in Austin, Texas, and was the Vascular Solutions sales rep for Austin and the surrounding territory prior to being promoted in or about January 2009. Charles Judice preceded Mr. Carlson as Regional Manager.

90. After being promoted to Regional Manager, Shane Carlson held his first regional meeting in Austin, Texas in or about March 2009. Relator attended the meeting, along with (among others) the Western Texas and New Mexico Vascular sales representative Eddie Pedregon; Kevin Brune, a sales rep who covered the Dallas area; John Osterman, a sales rep who covered the Houston area; Lisa Duffy, a sales rep who covered (at various times) San Antonio and Fort Worth; Mike Mullin, a sales rep who covered the Phoenix area, and clinical trainer John Fox. The meeting was held at an Embassy Suites hotel in Austin.

91. At the meeting, Shane Carlson instructed the sales reps how they were to market Vari-Lase for perforator vein treatment. In substance and in part, Carlson acknowledged that Vari-Lase was not indicated for such treatment; however, he instructed the sales reps to tell the

doctors that the product was not indicated for treatment of perforator veins, but that "we can't tell doctors how to practice medicine." Carlson's message was consistent with the message that had been continually communicated to sales reps by all levels of management at both the regional and the nationwide sales meetings.

92. As a result, when promoting Vari-Lase for the treatment of perforator veins to physicians, Relator and other Vascular sales representatives complied with management's instructions; while acknowledging that the "short kits" were not indicated for that purpose, they suggested such a use while telling doctors that they could employ the kits off-label if they so chose. Alternatively, the sales reps promoted the product for perforator-vein treatment without mentioning whether the kits were indicated for such use. Either way, at the urging of management, the sales reps did not discuss the potential risks of using Vascular products in the treatment of perforator veins.

b. Procedure Training for Unapproved Use.

93. Vascular also promotes the off-label use of its products by having its sales and clinical representatives throughout the U.S. train physicians in how to use Vari-Lase products off-label to treat perforator veins, including being present in the operating room while procedures are taking place. Many of these employees have little or no medical education, training or experience apart from their employment as Vascular sales reps.

94. For example, Utah Sales Representative Daniel McIff traveled throughout the West Coast training physicians to use Vari-Lase products in the treatment of perforator veins. Upon information and belief, Daniel McIff has no formal medical training. He is listed as the co-author of a 1996 article on endovascular aortic aneurysm repair (EVAR) with, among others, "E. Bruce McIff, M.D." Daniel McIff's author listing states only that he is "from the

Intermountain Vein Center, Provo, Utah" but does not indicate any medical degree, licensing or training. (E. B. McIff et al., *EVAR in Community Hospitals*, Endovascular Today, May 2006). It appears from public records that Daniel McIff may have worked as an assistant in a vein surgery clinic run by E. Bruce McIff, who may be his father or other close relative.

95. Similarly, Texas Clinical Specialist John Fox has only limited medical training, as a "scrub tech." Nonetheless, he often trained Texas physicians in the use of Vari-Lase products, including use for the treatment of perforator veins, including assisting them in the operating room. One physician whom Fox trained in this manner was Dr. Ammar Jarrous of the Amarillo Laser Vein Clinic.

96. In addition, Vascular pays vascular surgeons to train other physicians in the use of Vari-Lase products for the off-label treatment of perforator veins.

97. For example, Seattle-based vascular surgeon Daniel Pepper, M.D. ("Dr. Daniel Pepper") was paid by Vascular to train physicians in the use of the Vari-Lase procedure and products for the treatment of veins, including perforator veins, despite the lack of FDA clearance and the potential risk of patient harm.

c. Billing Instruction for Unapproved Use.

98. According to Relator, Vascular directs its sales representatives to instruct physicians performing perforator treatments to use the reimbursement codes approved by CMS for the treatment of superficial veins, for procedures involving perforator veins.

99. In fact, Vascular Regional Sales Directors have even circulated sample reimbursement letters to physicians, which had been successfully used by other doctors, instructing the physicians to submit the same reimbursement claims to the Government in order to obtain reimbursement for laser ablation treatment, including treatment of perforator veins.

100. For example, upon information and belief, the Ciao Bella Medical Spa and Vein Clinic in Chandler, Arizona, has submitted Vascular circulated reimbursement letters to Mercy Care, a managed care organization that provides health care services to people in Arizona's Medicaid program, in order to obtain reimbursement for laser ablation procedures using Vari-Lase products.

101. Further, Vascular representatives have been instructed to recommend that physicians treat a patient's individual veins on separate days so as to be reimbursed at the highest rate possible, as the HCPCS reimbursement rate for additional veins is lower than the rate for the first vein treated on a given day.

2. Enabling Reuse of Single-Use Only Fibers.

102. Vascular Bright Tip Fibers, and predecessor bare tip laser fibers, are disposable, single-use products.

103. The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, however, it must provide data demonstrating to the FDA that the device can be cleaned and sterilized without impairing its function.

104. Thus, if a device is labeled single-use, the manufacturer either chose not to conduct the necessary studies to enable the product to be labeled re-usable, or was aware that the product could not safely and reliably be used more than once.

105. Upon information and belief, since at least 2006, Vascular has tacitly encouraged the re-use of its single-use fibers by making them available for purchase separately from the less expensive sheaths through which they must be passed as part of the laser procedure.

106. Whereas physicians must buy sheaths and fibers together as part of procedure kits from Vascular's competitors at a cost of approximately $350, physicians are able to buy Vari-Lase sheaths, at a cost of approximately $95 to $135, without purchasing new fibers, and thus may re-use the expensive single-use fibers for multiple procedures.

107. Upon information and belief, Vascular intentionally designed its sales of these products in this fashion in order to increase the number of physicians who buy the Vari-Lase laser sheaths, and is well aware of physicians' routine re-use of the single-use fibers.

108. According to Relator, physicians' re-use of the single-use fibers was often discussed on sales representative calls and in conversations between sales representatives and between sales representatives and their client physicians.

109. According to Relator, vascular surgeon Dr. Daniel Pepper purchased approximately one hundred Vari-Lase fibers per year from Vascular Solutions, but performed approximately one hundred surgeries per month using the Vari-Lase endovenous vein procedure.

110. Upon information and belief, "fiber-less" procedure kits represent approximately 40% of sales of all Vari-Lase procedure kits. Since no competing vein therapy companies sell laser fibers separately from their accompanying sheaths, it is unlikely that doctors are acquiring their laser fibers elsewhere.

111. Upon information and belief, approximately 30% to 40% of Vari-Lase laser ablation procedures are performed with re-used single-use laser fibers, despite the fact that the re-use of single-use fibers renders the procedures less effective and risks patient harm through the potential transfer of dangerous blood halogens.

3. Kickbacks.

112. Vascular Solutions pays illegal kickbacks to physicians in the form of free procedure kits and other supplies with the purchase of Vari-Lase laser consoles in violation of the Anti-Kickback Statute.

113. Vascular has routinely provided upwards of $5,000 worth of free procedure kits and supplies to physicians who purchase its $26,000 to $34,000 laser console.

114. According to Relator, during his employment with Vascular, Relator was encouraged by Regional Sales Director Kip Theno to offer this "under-the-table incentive" to physicians.

115. For example, Dr. Edgardo Zaval-Alarcon M.D., owner of the Ciao Bella Medical Spa and Vein Clinic, was given $5,000 worth of free laser procedure kits, distributed over the course of a year, as incentive to buy the Vari-Lase laser console, which he purchased from Vascular in May of 2008.

116. The free procedure kits were not reflected on the product price quotes provided to the physicians, and were inventoried by Vascular as sample or demonstration kits.

B. Damages Caused by Vascular's Unlawful Marketing Schemes.

117. As described herein, Vascular violated the federal and state False Claims Acts by engaging in fraudulent marketing, sales, and business practices which resulted in the federal and state governments paying for medical procedures they should not have paid for.

118. Upon information and belief, Vascular's off-label and otherwise deceptive marketing of its endovenous laser therapy products has resulted in damages to the government of approximately 20 million dollars.

119. In marketing its Vari-Lase medical devices "off-label" and paying kickbacks to physicians in the form of free devices and supplies, Vascular violated applicable statutes and regulations, including, but not limited to, the federal Food, Drug, and Cosmetic Act and Anti-Kickback Statute, as well as parallel provisions of state law.

120. By marketing "off-label" uses of its medical devices and laser treatments for perforator veins, Vascular encouraged potentially unsafe surgical procedures which were not in accordance with FDA regulations. A potential risk of using laser therapy techniques to treat perforator veins is the development of deep vein thrombosis, the formation of a blood clot in a deep vein, that can cause pain and swelling in the leg and, if the clot dislodges and travels to the lung, a pulmonary embolism. Further, perforator veins have a tendency to reopen after laser treatment, rendering the treatment ineffective.

121. By tacitly encouraging multiple-use of laser fibers which have only been cleared by the FDA for single-use, Vascular also encouraged potentially unsafe and ineffective laser procedures. Laser fibers degrade and become less effective with use, rendering the energy delivery to the vein insufficient, and increasing the risk that the diseased vein will not close and that the procedure will need to be repeated. Further, re-using laser fibers risks the transfer of blood halogens to patients, which can cause Hepatitis C or other blood diseases.

122. In providing kickbacks to physicians in the form of free procedure kits and supplies, Vascular undermined physicians' and patients' choice of appropriate surgical procedures, creating the potential for patient harm. Patients who were advised to undergo Vascular's endovenous laser procedure had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether their doctors were instead influenced by unlawful incentives provided by Vascular.

123. Because of Vascular's illegal kickbacks, doctors more frequently prescribed Vascular's laser procedures for Medicaid and Medicare patients and beneficiaries of other government healthcare programs than they may have otherwise, in violation of federal law.

124. Vascular's illegal actions resulted in physicians submitting reimbursement claims to Medicaid, Medicare and other government healthcare programs and obtaining millions of dollars worth of payments from the United States and the various States. Under the False Claims Act, such claims were fraudulent because they sought reimbursement for medical supplies and procedures which were utilized as a result of illegal marketing and incentives. Had government-funded health insurance programs been aware that the medical devices were employed, and the procedures performed, as a result of the conduct alleged in this Complaint, they would not have paid the claims submitted as a result of Defendant's wrongdoing.

VII. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1)(A))

125. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

126. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendant has knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(1)(B))

127. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

128. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendant has knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by defendant – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False Record
Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(1)(G))

129. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

130. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendant knowingly made, used or caused to be made or used false records or false statements—*i.e.*, the false certifications made or caused to be made by defendant—material to an obligation to pay or transmit money to the Government or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

FOURTH CAUSE OF ACTION

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(1)(C))

131. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if full set forth herein. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendant conspired to make or present false or fraudulent claims and performed one or more acts to effect payment of false or fraudulent claims.

FIFTH CAUSE OF ACTION

(Violations of Anti-Kickback Statute)
(42 U.S.C. § 1320a-7a)

132. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

133. By engaging in the conduct described in the foregoing Paragraphs, the Defendant has violated 42 U.S.C. § 1320a-7a and 42 C.F.R. § 1001.952(f).

134. In particular, the Defendant has knowingly caused to be submitted claims to the United States Government and to Medicaid as a result of the payment of the above-described kickbacks. The payment of kickbacks to induce purchases constitutes remuneration to increase the level of business in violation of the anti-kickback statute.

135. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for medical procedures which, had the Government known were utilized as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

SIXTH CAUSE OF ACTION

(California False Claims Act)
(Cal. Govt. Code § 12651 *et seq.*)

136. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

137. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

138. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

139. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

140. By reason of the Defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

141. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

SEVENTH CAUSE OF ACTION

(Delaware False Claims and Reporting Act)
(Del Code Ann. tit. 6, § 1201 *et seq.*)

142. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

143. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

144. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

145. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

146. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

147. Pursuant to Del Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

EIGHTH CAUSE OF ACTION

(Florida False Claims Act)
(Fla. Stat. Ann. § 68.081 *et seq.*)

148. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

149. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

150. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

151. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

152. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

153. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

NINTH CAUSE OF ACTION

(Georgia False Medicaid Claims Act)
(Ga. Code. Ann. § 49-4-168.1 *et seq.*)

154. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

155. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

156. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

157. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

158. By reason of the Defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

159. Pursuant to Ga. Code. Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TENTH CAUSE OF ACTION

(Hawaii False Claims Act)
(Haw. Rev. Stat. § 661-21 *et seq.*)

160. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

161. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

162. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

163. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

164. By reason of the Defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

165. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

ELEVENTH CAUSE OF ACTION

(Illinois Whistleblower Reward and Protection Act)
(740 Ill. Comp. Stat. § 175/1 *et seq.*)

166. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

167. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

168. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

169. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

170. By reason of the Defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

171. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWELTH CAUSE OF ACTION

(Indiana False Claims and Whistleblower Protection Act)
(Ind. Code § 5-11-5.5-1 *et seq.*)

172. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

173. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

174. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

175. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

176. By reason of the Defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

177. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

THIRTEENTH CAUSE OF ACTION

(Louisiana Medical Assistance Programs Integrity Law)
(La. Rev. Stat. Ann. § 46:439.1 *et seq.*)

178. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

179. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

180. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

181. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

182. By reason of the Defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

183. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

FOURTEENTH CAUSE OF ACTION

(Massachusetts False Claims Law)
(Mass. Gen. Laws ch. 12, § 5A *et seq.*)

184. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

185. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

186. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

187. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

188. By reason of the Defendant's acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

189. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

FIFTEENTH CAUSE OF ACTION

(Michigan Medicaid False Claims Act)
(Mich. Comp. Laws § 400.601 *et seq.*)

190. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

191. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

192. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

193. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

194. By reason of the Defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

195. Pursuant to Mich. Stat. § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud, three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

SIXTEENTH CAUSE OF ACTION

(Nevada False Claims Act)
(Nev. Rev. Stat. § 357.010 *et seq.*)

196. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

197. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

198. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

199. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

200. By reason of the Defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

201. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

SEVENTEENTH CAUSE OF ACTION

(New Hampshire False Claims Act)
(N.H. Rev. Stat. Ann. § 167:61-b)

202. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

203. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

204. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

205. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

206. By reason of the Defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

207. Pursuant to § 167:61-b, the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

EIGHTEENTH CAUSE OF ACTION

(New Jersey False Claims Act)
(N.J. Stat. Ann. § 2A:32C-1 *et seq.*)

208. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

209. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

210. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

211. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

212. By reason of the Defendant's acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

213. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty allowed under the federal False Claims Act, 31 U.S.C. § 3729, for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

NINETEENTH CAUSE OF ACTION

(New Mexico Medicaid False Claims Act and Fraud Against Tax Payers Act)
(N.M. Stat. Ann. § 27-14-1 *et seq.* and § 44-9-1 *et seq.*)

214. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

215. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

216. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

217. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

218. By reason of the Defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

219. Pursuant to N.M. Stat. Ann. § 27-14-4 and § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTIETH CAUSE OF ACTION

(New York False Claims Act)
(N.Y. State Fin. Law § 187 *et seq.*)

220. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

221. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

222. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

223. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

224. By reason of the Defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

225. Pursuant to N.Y. State Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY FIRST CAUSE OF ACTION

(Oklahoma Medicaid False Claims Act)
(63 Okla. St. Ann. § 5053 *et seq.*)

226. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

227. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

228. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

229. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

230. By reason of Defendant's acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

231. Pursuant to 63 Okla. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY SECOND CAUSE OF ACTION

(The State False Claims Act (Rhode Island))
(R.I. Gen. Laws § 9-1.1-1 *et seq.*)

232. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

233. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

234. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

235. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

236. By reason of the Defendant's acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

237. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY THIRD CAUSE OF ACTION

(Tennessee Medicaid False Claims Act)
(Tenn. Code Ann. § 71-5-181 *et seq.*)

238. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

239. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

240. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

241. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

242. By reason of Defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

243. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY FOURTH CAUSE OF ACTION

(Texas Medicaid Fraud Prevention Law)
(Tex. Hum. Res. Code Ann. § 36.002)

244. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

245. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

246. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

247. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

248. By reason of the Defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

249. Pursuant to Tex. Hum. Res. Code Ann. § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY FIFTH CAUSE OF ACTION

(Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. § 8.01-216.1 *et seq.*)

250. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

251. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia Commonwealth Government for payment or approval.

252. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia Commonwealth Government to approve and pay such false and fraudulent claims.

253. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

254. By reason of Defendant's acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

255. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY SIXTH CAUSE OF ACTION

(Wisconsin False Claims for Medical Assistance Law)
(Wisc. Stat. § 20.931)

256. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

257. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

258. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

259. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

260. By reason of the Defendant's acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

261. Pursuant to Wisc. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

TWENTY SEVENTH CAUSE OF ACTION

(District of Columbia False Claims Act)
(D.C. Code Ann. § 2-308.03 *et seq.*)

262. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 124 of this Complaint as if fully set forth herein.

263. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

264. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

265. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

266. By reason of the Defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

267. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

VIII. DEMANDS FOR RELIEF

WHEREFORE, Relator, on behalf of the United States Government, demands judgment against the Defendant, ordering that:

As to the Federal Claims:

a. Pursuant to 31 U.S.C. § 3729(a), Defendant pays an amount equal to three times the amount of damages the United States Government has sustained because of Defendant's actions, plus a civil penalty of not less than $5,000 and not more than $10,000 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729, *et seq*; $50,000 for each violation of 42 U.S.C. § 1320a-7a(a)(7) of the Medicare/Medicaid Anti-Kickback Statute; and $15,000 for each violation of 21 U.S.C. §360 of the of the Food, Drug and Cosmetic Act, not to exceed $1,000,000;

b. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law; and

d. Relator be awarded such other and further relief as the Court may deem to be just and proper.

As to the State Claims:

e. Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a result of Defendant's actions, as well as the maximum statutory civil penalty for each violation by Defendants within each State, all as provided by:

Cal. Govt. Code §12651;
6 Del. C. § 1201;

Fla. Stat. Ann. § 68.082;
Ga. Code Ann. § 49-4-168.1;
Haw. Rev. Stat. § 661-21;
740 Ill. Comp. Stat. § 175/3;
Ind. Code § 5-11-5.5-2 ;
La. Rev. Stat. § 46:438.6;
Mass. Gen. Laws Ch. 12 § 5B;
Mich. Comp. Laws § 400.612;
Nev. Rev. Stat. Ann. § 357.040;
N.H. Rev. Stat. Ann. § 167-61-b;
N.J. Stat. Ann. § 2A:32C-3;
N.M. Stat. Ann. § 27-14-4 and § 44-9-3;
N.Y. Fin. Law § 189.1(g);
63 Okla. St. Ann. § 5053.1;
R.I. Gen. Laws § 9-1.1-3;
Tenn. Code Ann. § 71-5-182;
Va. Code Ann. § 8.01-216.3;
Wisc. Stat. § 20.931(2);
D.C. Code Ann. § 2-308.14; and

f. Relator and Plaintiff State of Texas be awarded statutory damages in an amount equal to two times the amount of actual damages that Texas has sustained as a result of the defendant's actions within Texas, as well as the maximum statutory civil penalty for each violation of Tex. Hum. Res. Code Ann. § 36.052;

g. Relator be awarded his Relator's share of any judgment to the maximum amount provided pursuant to:

Cal. Govt. Code § 12652(g)(2);
6 Del. C. § 1205;
Fla. Stat. Ann. § 68.085;
Ga. Code. Ann. § 49-4-168.2(i);
Haw. Rev. Stat. § 661-27;
740 Ill. Comp. Stat. § 175/4(d);
Ind. Code § 5-11-5.5-6;
La. Rev. Stat. § 46:439.4;
Mass. Gen. Laws Ch. 12 § 5F;
Mich. Comp. Laws § 400.610a;
Nev. Rev. Stat. Ann. § 357.210;
N.H. Rev. Stat. § 167:61-e;
N.J. Stat. Ann. § 2A:32C-7;
N.M. Stat. Ann. § 27-14-9 and § 44-9-7;

N.Y. State Fin. Law § 190.6;
63 Okla. St. Ann. § 5053.4;
R.I. Gen. Laws § 9-1.1-4;
Tenn. Code Ann. § 71-5-183;
Tex. Hum. Res. Code Ann. § 36.110;
Va. Code Ann. § 8.01-216.7;
Wisc. Stat. § 20.931(11); and
D.C. Code Ann. § 2-308.15;

h. Relator be awarded all costs and expenses associated with each of the pendent State claims, plus attorney's fees as provided pursuant to:

Cal. Govt. Code § 12652(g)(8);
6 Del. C. § 1205;
Fla. Stat. Ann. § 68.086;
Ga. Code. Ann. § 49-4-168.2(i);
Haw. Rev. Stat. § 661-27;
740 Ill. Comp. Stat. § 175/4(d);
Ind. Code § 5-11-5.5-6;
La. Rev. Stat. § 46:439.4;
Mass. Gen. Laws Ch. 12 § 5F;
Mich. Comp. Laws § 400.610a;
Nev. Rev. Stat. Ann. § 357.180;
N.H. Rev. Stat. § 167:61-e;
N.J. Stat. Ann. § 2A:32C-8;
N.M. Stat. Ann. § 27-14-9 and § 44-9-7;
N.Y. State Fin. Law § 190.7;
63 Okla. St. Ann. § 5053.4;
R.I. Gen. Laws § 9-1.1-4;
Tenn. Code Ann. § 71-5-183;
Tex. Hum. Res. Code Ann. § 36.110;
Va. Code Ann. § 8.01-216.7;
Wisc. Stat. § 20.931(11); and
D.C. Code Ann. § 2-308.15;

i. Relator and the State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

Dated: November 19, 2010

KENDALL LAW GROUP LLP

By: Jamie McKey

JOE KENDALL
State Bar No. 11260700
JAMIE MCKEY
State Bar No. 24045262
3232 McKinney, Suite 700
Dallas, Texas 75204
Telephone: (214) 744-3000
Facsimile: (214) 744-3015

STONE & MAGNANINI LLP

By: David S. Stone w/permission

David S. Stone
Robert A. Magnanini
Eric H. Jaso
150 John F. Kennedy Parkway
4th Floor
Short Hills, New Jersey 07078
(973) 218-1111

Attorneys for Relator